

REMARKS

The present communication responds to the Office Action dated July 28, 2004. In that Office Action, the Examiner rejected claims 1-20 as anticipated by US Patent 5,514,097 ("Knauer"). This rejection is respectfully traversed in view of the above amendments and because Knauer fails to disclose, at least, a container or reservoir mounted in a housing such that the container or reservoir is prevented from shifting and/or first and second shifting stages together forming a first spindle drive, rotational movement of which causes the first shifting stage to shift.

Rejection under 35 U.S.C. § 102

Claims 1-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent 5,514,097. This rejection is traversed at least for the following reasons.

Knauer discloses an injection apparatus wherein, upon activation of the apparatus, the needle is thrust forward, pushing the needle tip outside the needle shroud with enough force to puncture the skin, the needle thus being automatically introduced into the tissue. *Knauer Abstract*. Knauer explains that the patient is thereby spared the trauma of manually introducing an exposed needle into his or her own tissue. *Knauer, Column 3, lines 10-12*. Knauer explains that the injection apparatus includes a plurality of assemblies, all of which move from a first position to a second position, to obviate the need for manually injecting the needle into the skin:

A medicament injection assembly, that includes a plurality of assemblies including, for example, a medicament cartridge assembly and a variable dosing assembly, is movably mounted within the housing so that upon engagement and activation of a motive force that is supplied by the medicament injection assembly, the plurality of assemblies move from a first position to a second position. This motion, which is supplied by a thrusting assembly, moves not only the entire plurality of assemblies but also subassemblies and parts within those plurality of assemblies to deliver the desired dose of medicament. In contrast, typically in prior systems, the only movement was of parts required to deliver a dose and movement of entire assemblies was not provided because the user manually injected the needle into the skin. *Knauer, Column 3, lines 25-40*.

Thus, a plurality of assemblies including a medicament cartridge assembly and a variable dosing assembly are configured to move from a first position to a second position.

Claims 1 and 16, as amended, require a container to be mounted in the housing such that the container is prevented from shifting. Similarly, claim 15, as amended, requires a reservoir to be mounted in the housing such that the reservoir is prevented from shifting. Knauer teaches away from this, instead teaching a medicament cartridge assembly configured to move from a first position to a second position. For at least this reason, Knauer does not anticipate claims 1, 15 or 16.

The Examiner refers to element 317 of Figure 5A as being a first shifting stage. Figure 5A is an enlarged cross section of medicament cartridge assembly 305 of Figure 3. *Knauer, Column 11, lines 2-3*. Element 317 is a pushrod piston head 317 of a pushrod assembly 306A of a variable dosing assembly 306, Knauer explains:

Medicament cartridge assembly 305 contains a medicament ... Variable dosing assembly 306 interacts with medicament cartridge assembly 305 through pushrod assembly 306A, which includes pushrod 316 with pushrod piston head 317, and cartridge seat 318.
Knauer, Column 9, lines 43-44, 49-52.

The pushrod subassembly 306A, as part of the pushrod subassembly 306A, which is part of the variable dosing assembly 306, is forced forward when the medicament injection apparatus 200 is activated:

Pushrod subassembly 305A also interacts with automatic dosing assembly 307. Automatic dosing assembly 307 performs two functions. First, through motive force subassembly 300 of thrusting assembly 315, assembly 307 provides the force necessary to move variable dosing assembly 306, with pushrod subassembly 306A, and medicament cartridge assembly 305 forward when medicament injection apparatus 200 shifts from the “energized” e.g. retracted position, to the “activated” e.g. extended, position. *Knauer, Column 9, lines 56-64.*

Knauer describes pushrod piston head 317 as a circular disc having a flat surface 529A and a surface 529B, that is opposite flat surface 529A and is affixed to a first end 660A of pushrod 316. *Knauer, Column 14, lines 4-6.*

In addition to the bare element of a first shifting stage, claim 1 requires:

wherein the first and said second shifting stages, when seen in said advance direction of said piston, overlap at least in part, the first and second shifting stages together forming a

first spindle drive, a rotational movement of which causes the first shifting stage to shift... *Present application, Claim 1*

Similarly, claim 16 requires:

the first and second shifting stages together forming a first spindle drive, rotational movement of which causes the first shifting stage to shift... *Present application, claim 16.*

Accepting the Examiner's characterization of the pushrod piston head 317 as a first shifting stage, the first shifting stage of Knauer does not form, together with a second shifting stage, a first spindle drive, the rotational movement of which causes the first shifting stage to shift.

Indeed, the pushrod 316 itself is prevented from rotating:

Cartridge seat neck 318A has a shape such that it contacts only flat surfaces 650A, 650B of pushrod 316. This permits pushrod 316 to move smoothly through cartridge seat neck 318A, and at the same time prevents pushrod 316 from rotating. *Knauer, Column 14, lines 21-27.*

Thus, even if it were assumed that the Examiner intended to reference the pushrod 316 as the first shifting stage instead of merely the pushrod piston head 317, the pushrod 316 does not together with a second shifting stage form a first spindle drive, a rotational movement of which causes the first shifting stage to shift. Indeed, neither the pushrod piston head 317 nor the pushrod 316 of Knauer are intended to rotate.

Thus, as Knauer does not disclose a first shifting stage that, together with a second shifting stage, forms a first spindle drive, a rotational movement of which causes the first shifting stage to shift, Knauer does not anticipate claims 1 or 16.

For at least the reasons discussed above, it is respectfully submitted that Knauer does not anticipate claims 1, 15 or 16. As each of claims 2-14 and 17-20 depend either directly or indirectly from these claims, it is further submitted that Knauer does not anticipate claims 2-14 and 17-20. The dependent claims have also been amended for formal reasons. Thus, it is respectfully requested that the rejection of claims 1-20 be reconsidered and withdrawn.

New claims

New claims 24 – 30 have been added, are supported by the specification and the originally filed claims, and are allowable over Knauer and the documents (WO 97/00091 and WO 94/15660) cited on the Information Disclosure Statement submitted herewith.

In contrast to the injection apparatus of WO 97/00091, claim 24 is directed to an apparatus comprises a propelling device having a rotary driven drive member, a threaded sleeve and a shifting stage. The shifting stage is fixedly connected to the piston. The drive member is a threaded rod which protrudes from the proximal side, i.e., from the rear, into the threaded sleeve which surrounds it, and the shifting stage which also surrounds. Conversely, it follows from this that to be the rotary driven, the drive member/threaded rod must protrude proximally out of the two sleeves and of the propelling device. Therefore, when retracted, the propelling device exhibits an axial length in the advance direction of the piston which is at least composed of the length of the axially longest of the components and, additionally, of the length of the drive member.

This advantageously meets one object of the present invention: to provide a propelling device which takes up little space and, as a result, is particularly suitable for use as a propelling device for a portable medicament administering device.

By the drive member of the propelling device surrounding the two other members, as in new claim 24, a coupling element for introducing the rotary drive does not have to be guided out of the overlap region of the three members in the axial direction, i.e., in or counter to the advance direction of the piston, and axial length can therefore be saved as compared to the propelling device of WO 97/00091.

WO 97/00091 does not concern itself with ways of reducing length. At least this is not explicitly mentioned and the document, therefore, does not provide any suggestion which would lead in an obvious way to subject claimed in the present application. The disclosure and teachings of WO 94/15660 and the other references of record in no way remedy the failure of WO 97/00091 to disclose or teach the present invention.

Conclusion

The above amendments generate additional claim fees, and a Petition for Extension of Time (for three months) is being submitted herewith. The Information Disclosure Statement submitted herewith also requires a fee. A check for all fees is enclosed, but the Office is also hereby authorized to charge any deficiencies and credit any overpayments with respect to this communication or the Petition to Deposit Account No. 04-1420.

This application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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Date:

July 28, 2005

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